
Standards for the Coverage of Organ Transplant Services

- b. Preparation and transplantation consisting of organ procurement, surgical procedures and all related medical care.
- c. Hospitalization related to the transplantation including the actual procedure and any subsequent related hospitalization (to include, but not limited to, rejection episodes, surgically related infections and bleeding episodes).
- d. Post-operative follow-up care and other professional services related to the transplantation including treatment of complications, outpatient visits and evaluations, medications and diagnostic services. Medications include outpatient self-administered immunosuppressant drugs.
- e. Catastrophic reinsurance for up to 100 days post-transplant, which includes coverage for medically necessary lodging and transportation.
- f. Pre-transplant dental evaluation and treatment for oral infection. (The service is limited to diagnosis and elimination of oral infection, and will commence only after the member has been established as an otherwise appropriate candidate.)
- g. Room and board for the member and one adult caregiver is provided during the time it is necessary for the member to remain in close proximity to the medical center.
- h. Transportation for the member and one adult caregiver is provided to and from the medical treatment during the time it is necessary for the member to remain in close proximity to the medical center.

Ventricular Assist Devices (VAD's) and related services are covered for all Title XIX members, when used as a bridge to a heart transplant, provided all the following criteria are met:

- a. The VAD must be used in accordance with the FDA approved labeling instructions;
- b. The member must be approved and listed as a candidate for heart transplantation by a Medicare approved heart transplant center that is registered with AHCCCS; and

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- c. The VAD is implanted by the approved heart transplant center for a member listed by that center. If the member is listed by another approved heart transplant center, the implanting center must receive written permission from the center with which the member is listed.

Once a VAD has been implanted as a bridge to heart transplantation, the member must be maintained on the VAD until such time as the heart transplantation is performed, the member expires or the member no longer requires the VAD as a bridge to the heart transplantation.

E. Kidney Transplantation

1. Medically necessary kidney transplantation is an AHCCCS covered service for AHCCCS members.
2. Kidney transplantation is a procedure in which a kidney is harvested from a living or cadaveric human donor and transplanted into the member.
3. Medical necessity is established by the following criteria in those cases where AHCCCS is the primary payer:
 - a. The eligible person or member has End Stage Renal Disease (ESRD) and he potential for successful transplantation.
 - b. The effectiveness of the proposed transplantation has been demonstrated and documented.
 - c. The stage of the disease is such that the transplantation can affect the outcome.
 - d. The subsequent recovery is not significantly compromised by other conditions including, but not limited to:
 - (1) Malignancy or active infectious disease.
 - (2) Irreversible disease of a major organ system (other than ESRD).
 - (3) Critical psychological conditions and compliance behavior which preclude a positive outcome.

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- (4) A primary disease process that would likely cause failure of any transplantation.
- e. The donor, (living or cadaver) must be blood group and crossmatch compatible.
- f. Plans for long-term adherence to a disciplined medical regimen are feasible and realistic for the potential candidate to whom the transplantation services will be provided.

The feasibility of a potential candidate's adherence to his or her medical regimen is determined through consultation with the Transplant Center where an extensive evaluation of the member, including psychological factors, has been conducted. In addition, consultation may be held with the AHCCCS Medical Director and one of more of the following: the Medical Director of the member's Health Plan or Program Contractor, the member's primary care provider, experts in medical ethics and/or the AHCCCS Kidney Transplantation Expert Committee.

4. Components of Service

Kidney transplantation involves the following services:

- a. Pre-transplant evaluation and typing of the candidate
- b. Search, via designated transplant centers, for a potential donor.
- c. Preparation and transplantation consisting of organ procurement, surgical procedures and all related medical care.
- d. Hospitalization related to the transplantation including the actual procedure and any subsequent related hospitalization (to include, but not limited to, rejection episodes, surgically related infections and bleeding episodes).
- e. Post-operative follow-up care and other professional services related to the transplantation including treatment of complications, outpatient visits and evaluations, medications and diagnostic services. Medications include outpatient self-administered immunosuppressant drugs.

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- f. Catastrophic reinsurance for up to 100 days post-transplant, which includes coverage for medically necessary lodging and transportation.
- g. Pre-transplant dental evaluation and treatment for oral infection. (The service is limited to diagnosis and elimination of oral infection, and will commence only after the member has been established as an otherwise appropriate candidate.)
- h. Room and board for the member and one adult caregiver is provided during the time it is necessary for the member to remain in close proximity to the medical center.
- i. Transportation for the member and one adult caregiver is provided to and from the medical treatment during the time it is necessary for the member to remain in close proximity to the medical center.

F. Liver Transplantation

- 1. Medically necessary liver transplantations and related services are covered for AHCCCS members.
- 2. Liver transplantation is a procedure in which the liver is harvested from a cadaveric human donor and transplanted into the member.
- 3. Medical necessity for liver transplantation is established by the following criteria:
 - a. The potential transplant recipient has end stage liver disease.
 - b. The prognosis for survival without transplantation is less than 12 months.
 - c. The potential for successful transplantation and subsequent recovery is not significantly compromised by other conditions including, but not limited to:
 - (1) Hepatitis B, surface antigen positive.
 - (2) Systemic infections unresponsive to treatment.
 - (3) Irreversible disease of another major organ system.
 - (4) Documented evidence of continuing substance abuse.
 - (5) Critical psychosocial conditions, behaviors or problems in adherence to a disciplined medical regimen which preclude a positive transplant outcome. (Transplant coverage decisions involving these matters will

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be made by the AHCCCS Medical Director in consultation with the health plan or program contractor Medical Director and the Liver Transplant Committee.)

- d. Plans for long-term adherence to a disciplined medical regimen are feasible and realistic for the potential candidate for transplantation services.

The feasibility of a potential candidate's adherence to his or her medical regimen is determined through consultation with the Transplant Center where an extensive evaluation of the member, including psychological factors, has been conducted. In addition, consultation may be held with the AHCCCS Medical Director and one of more of the following: the Medical Director of the member's Health Plan or Program Contractor, the member's primary care provider, experts in medical ethics and/or the AHCCCS Liver Transplantation Expert Committee.

4. Covered Conditions

Liver transplantation has accepted therapeutic value in the management of selected patients with, but not limited to, the following evidence of end-stage liver disease:

- a. Primary or secondary biliary cirrhosis.
- b. Primary sclerosing cholangitis.
- d. Postnecrotic cirrhosis, hepatitis B, surface antigen negative.
- d. Cirrhosis (Members with recent histories of substance abuse must document abstinence for the past six (6) months, and demonstrate current active participation in a formal rehabilitation program).
- e. Inborn errors in metabolism including, but not limited to: Alpha-1 antitrypsin deficiency disease, Wilson's disease, primary hemochromatosis.
- f. Extrahepatic biliary atresia.
- g. Budd Chiari syndrome or veno-occlusive disease.
- h. Cryptogenic cirrhosis.
- i. Acute hepatic failure

5. Components of Service

Preparation and transplantation, which consists of the following:

- a. Organ procurement
- b. Surgical procedure

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- c. All related medical care

Coverage of liver transplantation services includes the following components.

- a. Physical examination
- b. Psychological and social service evaluations, as indicated
- c. Laboratory imaging
- d. Diagnostic imaging
- e. Biopsies
- f. Nutritional assessment as indicated
- g. Pre-transplant dental evaluation and treatment for oral infection. (The service is limited to diagnosis and elimination of oral infection, and will commence only after the member has been established as an otherwise appropriate candidate.)

Inpatient and/or outpatient convalescent care, which includes the following:

- a. Laboratory studies
- b. Diagnostic imaging
- c. Biopsies, as indicated
- d. Treatment of complications
- e. Post-transplant discharge evaluations
- f. All related medication, including immunosuppressants
- g. Room and board for the member and one adult caregiver is provided during the time it is necessary for the member to remain in close proximity to the medical center
- h. Transportation for the member and one adult caregiver is provided to and from the medical treatment during the time it is necessary for the member to remain in close proximity to the medical center.
- i. Catastrophic reinsurance for up to 100 days post-transplant.

G. Lung and Heart/Lung Transplantation

- 1. Medically necessary lung and heart-lung transplantations, and related services are covered for AHCCCS members.
- 2. Lung transplantation refers to the transplantation of one or both lungs from a single cadaveric human donor. Heart-lung transplantation refers to the transplantation of one or both lungs and the heart from a single cadaveric donor.

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3. Only medically necessary human lung and/or heart-lung transplantation are covered. AHCCCS covers ventricular assist devices (VAD's) as a bridge to heart transplantation under the circumstances addressed in the heart transplantation section, item D of this attachment.
4. Medical necessity is established by the following criteria:
 - a. The potential candidate for transplantation services has irreversible, progressive, disabling end stage pulmonary disease, or end-stage cardiopulmonary disease.
 - b. A potential candidate is selected based upon both a critical, medical need and a strong likelihood of successful clinical outcome.
 - c. The effectiveness of the proposed transplantation has been demonstrated and documented.
 - d. The stage of the disease is such that the transplantation can affect the outcome.
 - e. All other medically appropriate medical and surgical therapies that might be expected to yield both short-term and long-term survival, comparable to that of transplantation, have been tried or considered.
 - f. Plans for long-term adherence to a disciplined medical regimen are feasible and realistic for the potential candidate for transplantation services.

The feasibility of a potential candidate's adherence to his or her medical regimen is determined through consultation with the Transplant Center where an extensive evaluation of the member, including psychological factors, has been conducted. In addition, consultation may be held with the AHCCCS Medical Director and one of more of the following: the Medical Director of the member's Health Plan or Program Contractor, the member's primary care provider, experts in medical ethics and/or the AHCCCS Lung and Heart/Lung Transplantation Expert Committee.

- g. The potential for successful transplantation and subsequent recovery is not significantly compromised by other conditions including, but not limited to:
 - (1) Primary or metastatic malignancies of the lung.

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- (2) Current significant acute illness that is likely to contribute to a poor outcome.
- (3) Current use of mechanical ventilation for more than a very brief period.
- (4) Significant or advanced heart, liver, kidney, gastrointestinal or other systemic or multi-system disease that is likely to contribute to a poor outcome after lung transplantation.
- (5) Significant extra-pulmonary infection.
- (6) Chronic pulmonary infection in a candidate only for single lung transplantation.
- (7) Continued cigarette smoking or failure to have abstained for at least one year prior to consideration for transplantation.

AHCCCS OMD consulted with experts in the field of pulmonary medicine and the medical directors of Health Plans and Program Contractors regarding an acceptable timeframe to indicate a low recidivism likelihood. The result of those consultations was that a period of at least one year would be long enough to indicate low likelihood of recidivism.

- (8) Systemic hypertension that requires more than two drugs for adequate control.
- (9) Cachexia, even in the absence of major end-organ failure.
- (10) Morbid obesity that could affect the outcome of the surgical procedure or the recovery of the member.
- (11) Previous thoracic or cardiac surgery, or other reason(s) for pleural adhesions.
- (12) Irreversible dysfunction of any other vital organ(s).
- (13) The member's age is beyond that at which there has been substantial favorable experience for successful transplantation.

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- (14) Chronic corticosteroid therapy that cannot be discontinued prior to transplantation, or tapered to a low dose (equivalent to 10 mg. prednisone per day).

5. Covered Conditions

Lung and/or heart-lung transplantation(s) have accepted therapeutic value in the management of selected candidates with, but not limited to, the following conditions listed below:

- a. Chronic obstructive pulmonary disease (COPD)/Emphysema.
- b. Alpha 1 - antitrypsin deficiency.
- c. Pulmonary fibrosis.
- d. Pulmonary hypertension.
- e. Eisenmenger's syndrome.
- f. Sarcoidosis.
- g. Cystic fibrosis.
- h. Bronchiectasis.
- i. Bronchiolitis obliteras.

6. Components of Service

Covered lung and heart-lung transplantation includes the transplantation and all services related to it, including, but not limited to:

- a. Pre-transplantation assessment and typing of the candidate.
- b. Preparation and transplantation consisting of surgical procedures, organ procurement and all related medical care.
- c. Hospitalization related to the transplantation, including the annual procedure and any subsequent related hospitalization and/or treatment of complications (to include, but not be limited to, rejection episodes, surgically related infections and bleeding episodes).
- d. Pre-transplant dental evaluation and treatment for oral infection. (The service is limited to diagnosis and elimination of oral infection, and will commence only after the member has been established as an otherwise appropriate candidate.)

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- e. Post-operative follow-up care and other professional services related to the transplantation, including outpatient visits, medications and diagnostic services. Medications include outpatient self-administered immunosuppressant drugs.
- f. Room and board for the member and one adult caregiver is provided during the time it is necessary for the member to remain in close proximity to the medical center
- g. Transportation for the member and one adult caregiver is provided to and from the medical treatment during the time it is necessary for the member to remain in close proximity to the medical center.

H. Pancreas after Kidney Transplantation

- 1. AHCCCS covers pancreas after kidney transplantation for eligible members. Pancreas after kidney transplantation is a procedure in which a member with a functioning kidney graft, or with the opportunity of receiving a kidney from a living donor, can proceed first with the kidney and then wait for a cadaver pancreas.

Pancreas after kidney transplantation (PAK) has an accepted therapeutic value in the management of selected patients with diagnosed Type 1 diabetes mellitus who have had a successful kidney transplantation.

- 2. Coverage of pancreas after kidney transplantation (PAK) services includes the following components.
 - a. Member pre-transplant evaluation (inpatient or outpatient), which consists of the following:
 - (1) Physical examination.
 - (2) Psychological and social service evaluations, as indicated.
 - (3) Laboratory studies, as indicated.
 - (4) Diagnostic imaging.